



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of

BARAUSKAS & TIBERG

Atty. Ref.: 613-109;

Appl. No. 10/568,778

TC/A.U. 1618

Filed: 23 Mar 2007

Examiner: AHMED

For: Non-Lamellar Compositions of DOPE and P80

\* \* \* \* \*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**EVIDENTIARY DECLARATION UNDER 37 CFR §1.132**

I, Fredrik TIBERG, one of the joint inventors in the above-identified application, do hereby declare:

1. That my residence and citizenship are of record in this application as stated in my declaration as inventor made under 37 C.F.R. §1.63 and that I am employed as President and Chief Scientific Officer of CAMURUS AB of Lund, Sweden, the assignee of the application.
2. That I am familiar with the contents of the above-identified application and the research effort underlying this application, and that I have read and am familiar with the Official Action of 9 July 2008.
3. That I am familiar with the contents of International patent publication WO 97/11682 in the name of Liu et al. (Liu), and with the compositions described therein, particularly in Table 2.
4. That I have investigated the phase behavior of mixtures of dioleoyl-phosphatidylethanolamine (DOPE) with polysorbate 80 (Tween 80 or P80) in water, which are

the subject of the above-identified application and have found that this phase behavior is greatly affected by the addition of significant proportions of other amphiphilic or lipiphilic components.

5. That Composition #17 illustrated in Table 2 of Liu consists of 1 part castor oil, 1 part Tween 80, 3 parts 3ss[N-(N', N'dimethylaminoethane) carbamoyl] cholesterol (DC-Chol), and one part dioleoyl-phosphatidylethanolamine (DOPE), thus having only two parts of those components indicated in the above-identified application in admixture with four parts of other components.

6. That since Composition #17 illustrated in Table 2 of Liu consists of primarily of the DC-Chol and castor oil mixture, which is the subject of Liu, with the addition of only 16% by weight of each of DOPE and P80, it would be expected that the phase behavior of this mixture would be primarily controlled by the mixtures of Liu with a significant effect coming from the larger content of DC-Chol and castor oil.


7. That the mixtures of Liu are described as "emulsion and micellar" formulations, and that this is structurally distinct from the non-lamellar formulations of the above-identified application, which comprise non-lamellar cubic, hexagonal or L<sub>3</sub> phase particles, or form such particles on exposure to aqueous fluids.

8. That in view of the above, the formulations of Liu, including Composition #17 can be expected to be emulsions or micellar formulations both from the disclosure of Liu itself and from the behavior of DOPE/P80 compositions studied in relation to the above-identified application.

I declare further that all statements made herein of my/our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date:

7<sup>th</sup> Jan 2007

  
Fredrik Tiberg